An Innovative Approach to Develop a Lead TRV and Cleanup Value Protective of the California Least Tern

NASNI IR Site 99

Presented By
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Objective

NAS North Island wants to develop an alternative nesting site to encourage the California Least Tern (CLT), an endangered species, colony to migrate to IR Site 9 to free up developable land.

- Human Health and Ecological Risk Assessments for soil show unacceptable risk to both but the ecological risk is the driver of the remediation footprint.
- Project is gridlocked over potential risk to the CLT using traditional risk assessment approaches to develop a lead cleanup value and a fresh approach is needed.
- EPA's Benchmark Dose (BMD) software used to develop a lead toxicity reference value (TRV) and cleanup value.
- Innovative approach provided a practical and reasonable cleanup value in the absence of an agreed upon ambient lead concentration in technically defensible manner.

CLT Alternative Nesting Area Overview

- Human access to the area is and will continue to be restricted due to the airfield and Weapons Compound's explosive safety arcs.
- All plants (except special plants), birds (non-tern species), and mammals will be removed from the area.

- Response action will address risk drivers for surface and subsurface (to 6 feet) soil.
- Backfill excavations and return area to Base for use as an Alternative CLT nesting site.

IR Site 9 Soil Eco Receptors Risk

Exposure Unit (EU) 1, surface soil

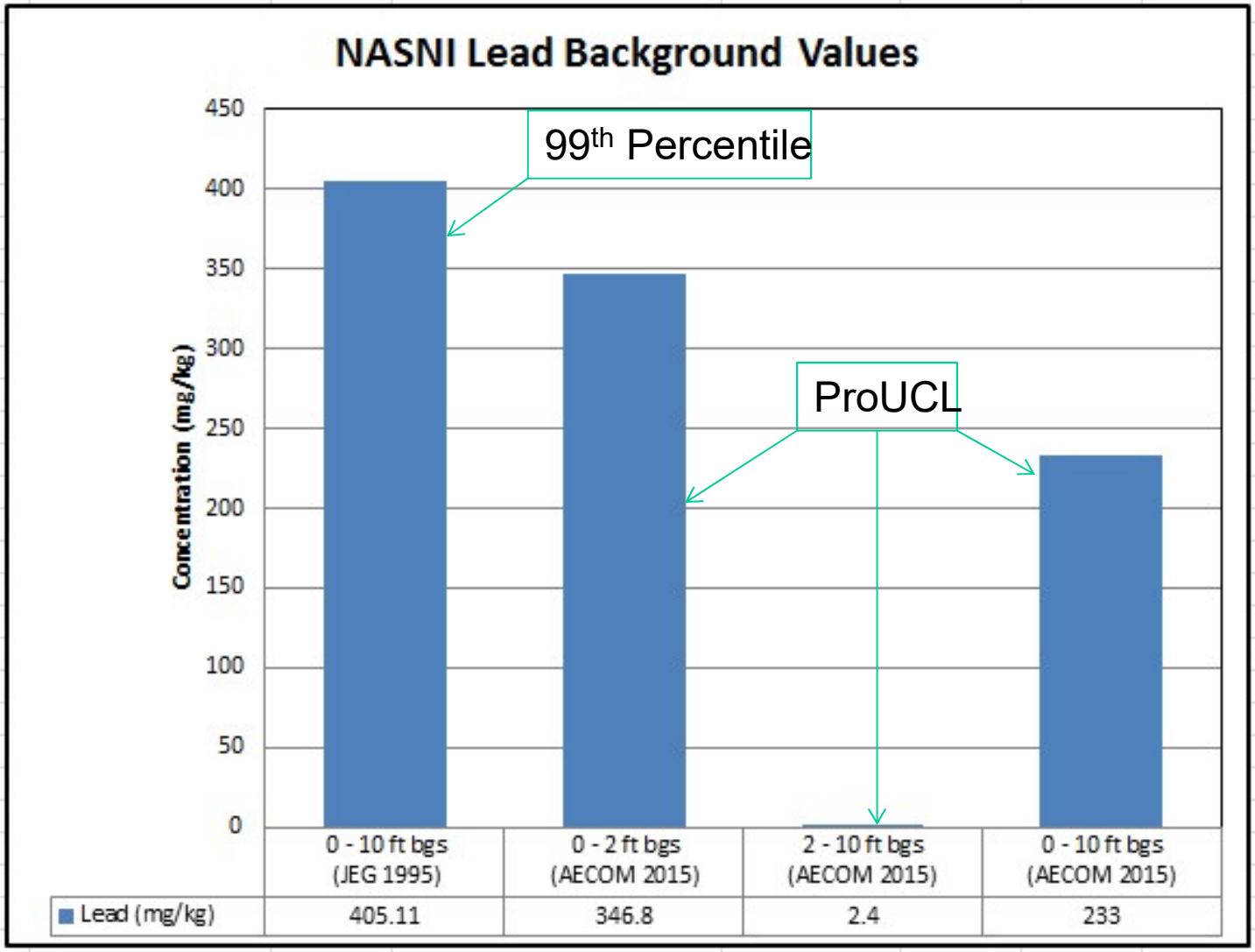
- CLT - No-observed-adverse-effect-level (NOAEL - low TRV) HQ > 1 and Lowest-observed-adverse-effect-level (LOAEL – high TRV) HQ>1 for lead
- No unacceptable risk – all lead soil concentrations are <405 mg/kg

EU 2, surface soil

- deer mouse - cadmium
- horned lark - cadmium, chromium, mercury, and lead
- burrowing owl - chromium, lead, DDT, and PCBs

EU 2, subsurface soil

- burrowing owl - chromium


NASNI Lead Background Values
99th Percentile
ProUCL
Concentration (mg/kg)
450
400
350
300
250
200
150
100
50
0
0 - 10 ft bgs (JEG 1995)
0 - 2 ft bgs (AECOM 2015)
2 - 10 ft bgs (AECOM 2015)
0 - 10 ft bgs (AECOM 2015)
Lead (mg/kg)
405.11
346.8
2.4
233

IR Site 9 Lead Distribution

Lead Distribution Summary

- With the exception of the areas along the boundaries of the proposed CLT nesting area, concentrations of lead are generally below 40 mg/kg and typically below 10 mg/kg.
- Areas with high lead concentrations coincide with elevated concentrations for other constituents.
- These areas are the focus of efforts to reduce the site-wide exposure point concentrations.
- Desk top removal exercise shows post-remediation lead site-wide concentration of <42 mg/kg.
- Regulatory agencies could not get past the 405 and 233 mg/kg values.

Lead PCL Development

- As part of scoping a removal action, the Navy developed lead preliminary clean up levels (PCLs) based on TRVs in an attempt to move the discussion beyond background.
- PCLs were developed specifically for the CLT different life stages.
- A range of available TRVs were used.

PCL - Adult (mg/kg)	PCL - hatchling (mg/kg)	PCL - juvenile (mg/kg)	PCL - hatchling/ juvenile (mg/kg)	Final PCL (mg/kg)	PCL Basis
191	843	224	177	**177**	PCL based on geometric mean of BTAG low and high TRVs (0.35 mg/kg-d)
7.7	33.7	9.0	7.1	7.1	PCL based on BTAG Low TRV(0.014 mg/kg-d)
4,785	21,074	5,605	4,428	4,428	PCL based on BTAG High TRV (8.75 mg/kg-d)
891	3,926	1,044	825	825	PCL based on EPA Eco-SSL NOAEL TRV (1.63 mg/kg-d)

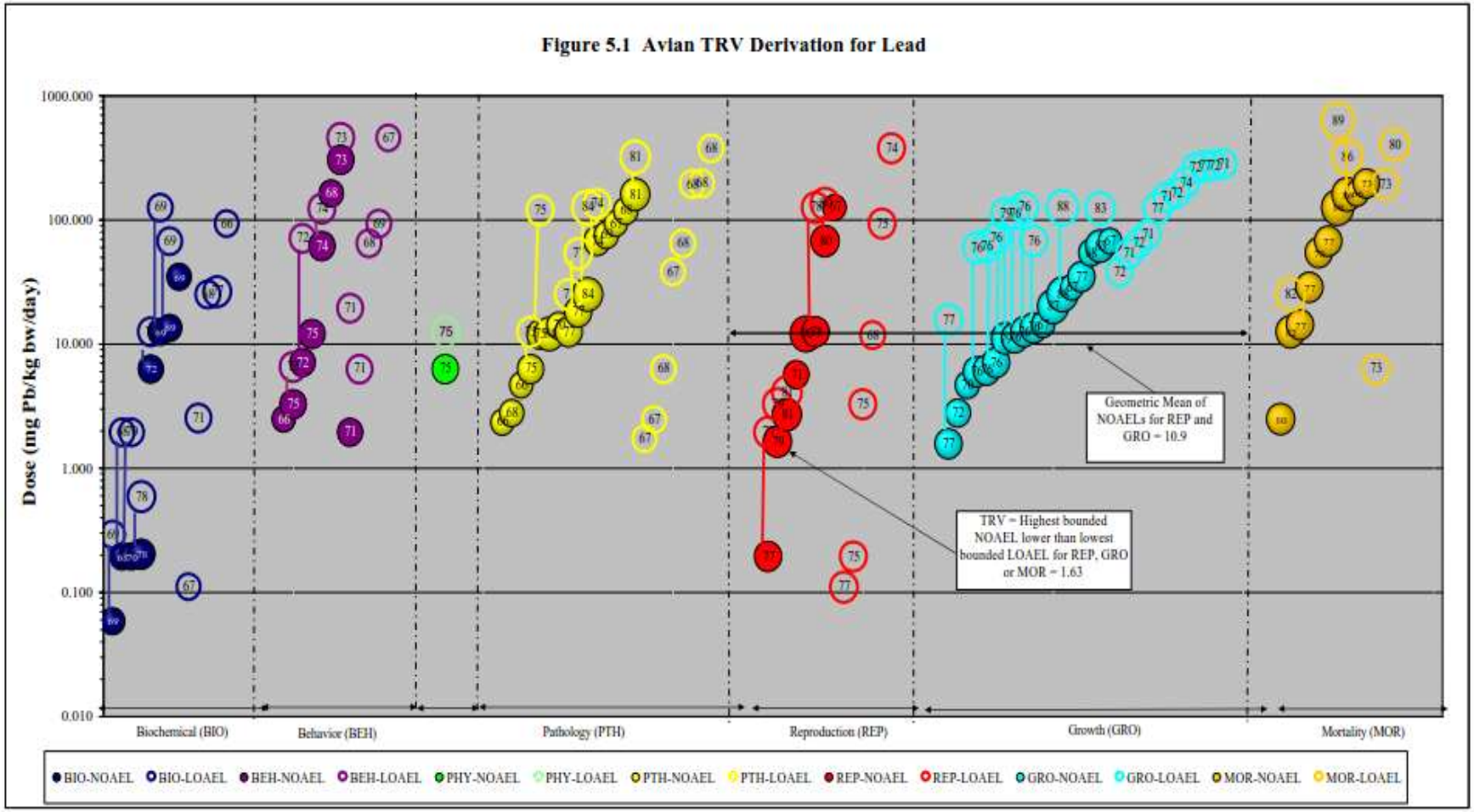
Lead TRV Comments from Agencies

- Comments questioned use of geometric mean of BTAG TRV-L and TRV-H for the CLT:
  - California Department of Fish and Wildlife does not accept geometric mean of NOAEL and LOAEL as a predictive metric
- Recommended use of EPA Region 9 BTAG TRV-L for PCL development because:
  - BTAG TRV-L is consensus-based and peer reviewed
  - exposure regimen for BTAG TRV-L benchmark study is similar to that assumed for newly hatched tern chicks
  - ten-fold factor used to adjust for uncertainty (to convert an effect level to a no effect level) is not excessive and is appropriate, especially when dealing with an endangered species
  - Typically results in an extremely low cleanup values or below background

Alternative TRV and PCL Development

- Needed a fresh approach, CLEAN contractor (100,000+ employees) unable to find assistance within their company, a call my Eco-whispherer resulted in a recommendation of the BDM.
- BDM is a Dose-response (D-R) model used as an alternative methodology to address concerns identified with BTAG TRV-L
- Used D-R model to develop protective TRV
  - Critical review of BTAG TRV-L TRVs used in the Eco-SSL – determine to have a great dose-response data set
  - Selected appropriate toxicological study for relevant endpoint
  - Develop D-R relationship
- Used exposure parameters and TRV to derive PCL for three life history stages of the CLT
  - Hatchling
  - Juvenile
  - Adult

Comparison to Toxicity Literature



- Eco-SSL avian NOAEL is 2 orders of magnitude higher than BTAG TRV-L →1.63 mg/kg-d
- Lowest NOAEL reported in Eco-SSL (bounded or unbounded) for REP, MOR, and GRO endpoints is 0.19 mg/kg-d
- Lowest NOAEL considering all endpoints reported is 0.058 mg/kg-d (biochemical endpoint)

Standard Methods to Develop TRVs

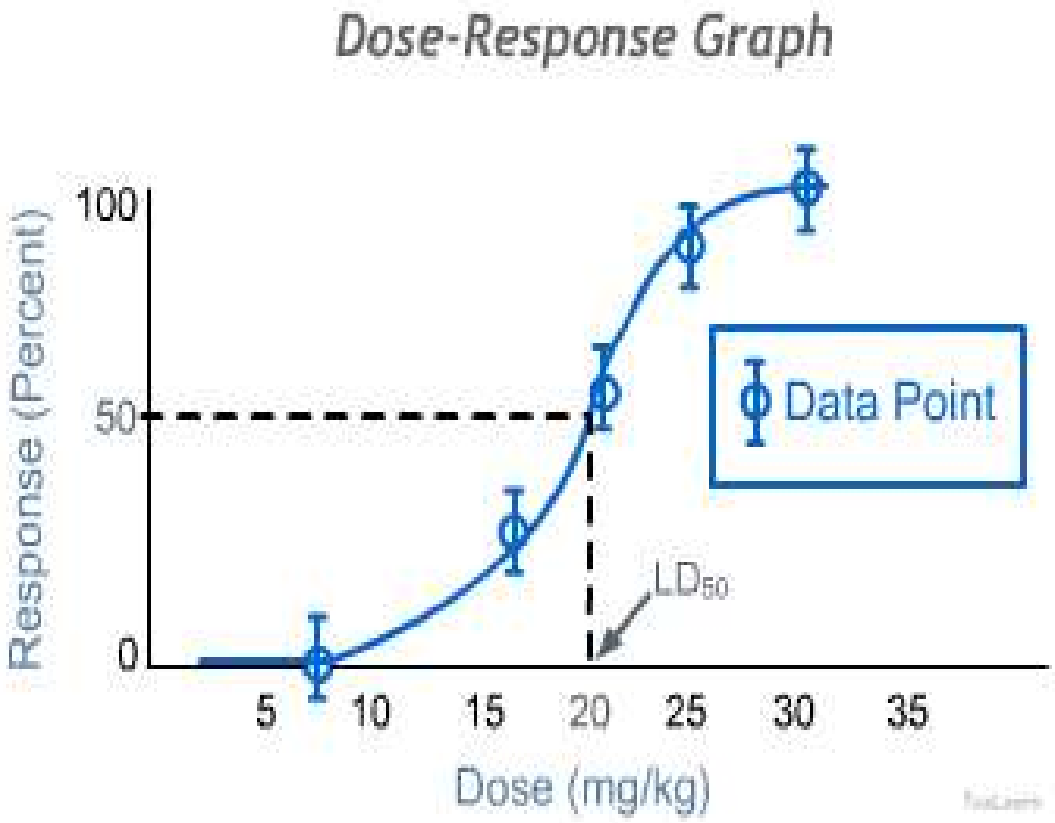
- Point estimates:
  - TRVs are typically based on reported point estimates:
    - NOAEL - the highest dose that does not cause a statistically significant adverse effect relative to control
    - LOAEL- the lowest dose that causes a statistically significant adverse effect relative to control
    - Statistically significant doses may not be ecologically relevant
  - Theoretically, the threshold for a given adverse effect lies between the NOAEL and the LOAEL
    - “Continuous” doses are not typically measured, and so the threshold for a given adverse effect is unknown)

Dose-Response Approach Overview

- Dose-Response (D-R) modeling:
  - Overcomes reliance on NOAEL and LOAEL dose levels that are chosen irrespective of the full set of study data
  - Uses all study doses for a given endpoint, response data, and statistical variability of the study measurements to construct a D-R curve
  - Eliminates need to use generic uncertainty factors
- Shape of the D-R curve allows for:
  - Derivation of single point estimates (e.g., effective concentration, ECx value)
  - Consideration of doses not used in the study – response is continuous
  - Better understanding of the likelihood and magnitude of potential effects and predicted response to incremental increases in exposure/dose

Typical Dose-Response Curve

- EPA Benchmark Dose (BMD) Software Version 2.6.0.1 (EPA 2015) tool was used to develop dose-response curve
- Per EPA BMD Technical Guidance (EPA 2012), a benchmark dose is:
  - *Exposure due to a dose of a substance associated with a specified low incidence of risk, generally in the range of 1% to 10% of a health effect; or dose associated with a specified measure or change of a biological effect"*

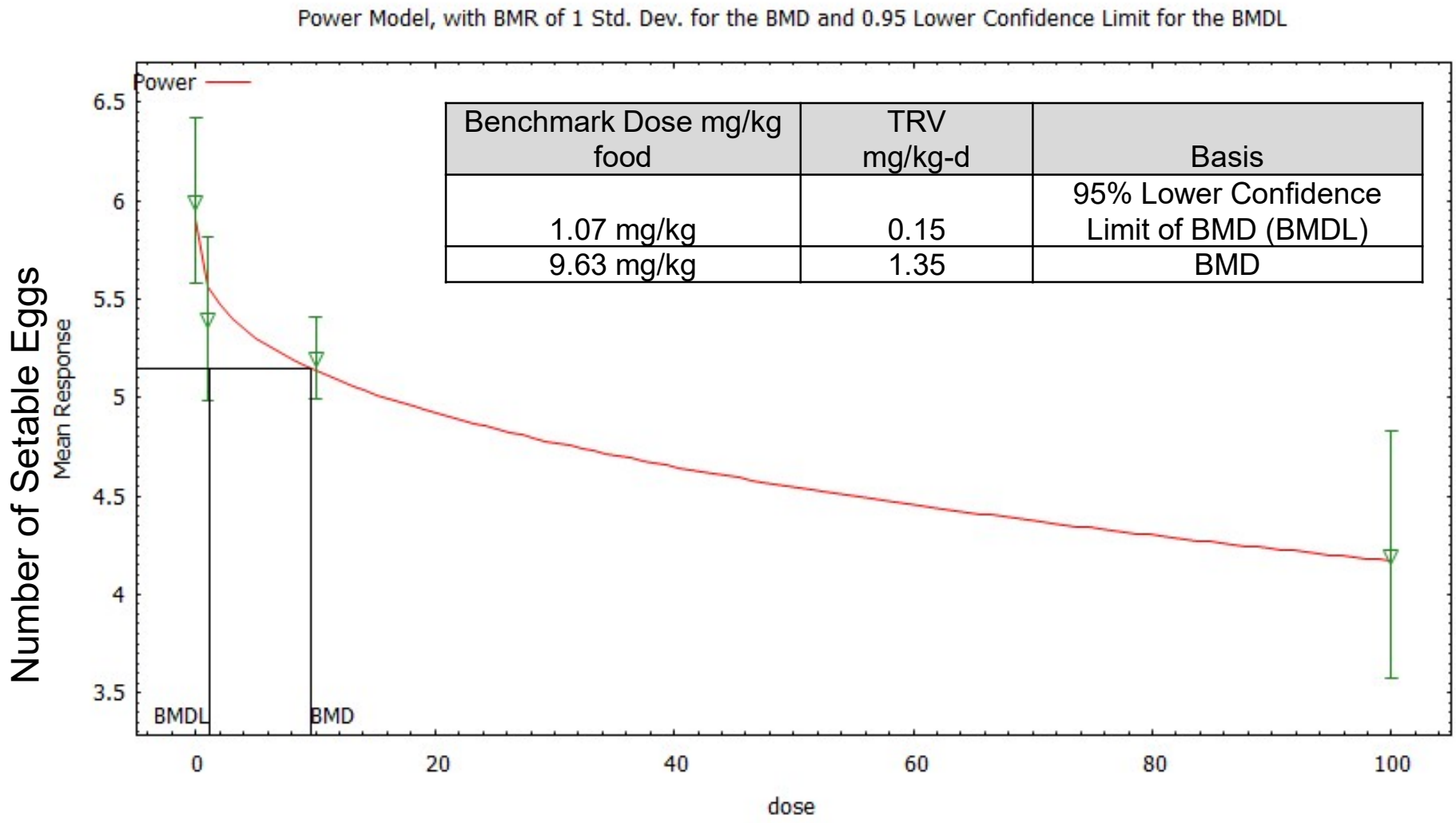


Source:https://toxlearn.nlm.nih.gov/htmlversion/module1.html#Dose-EffectandDose-Response

Development of TRVs from D-R Model

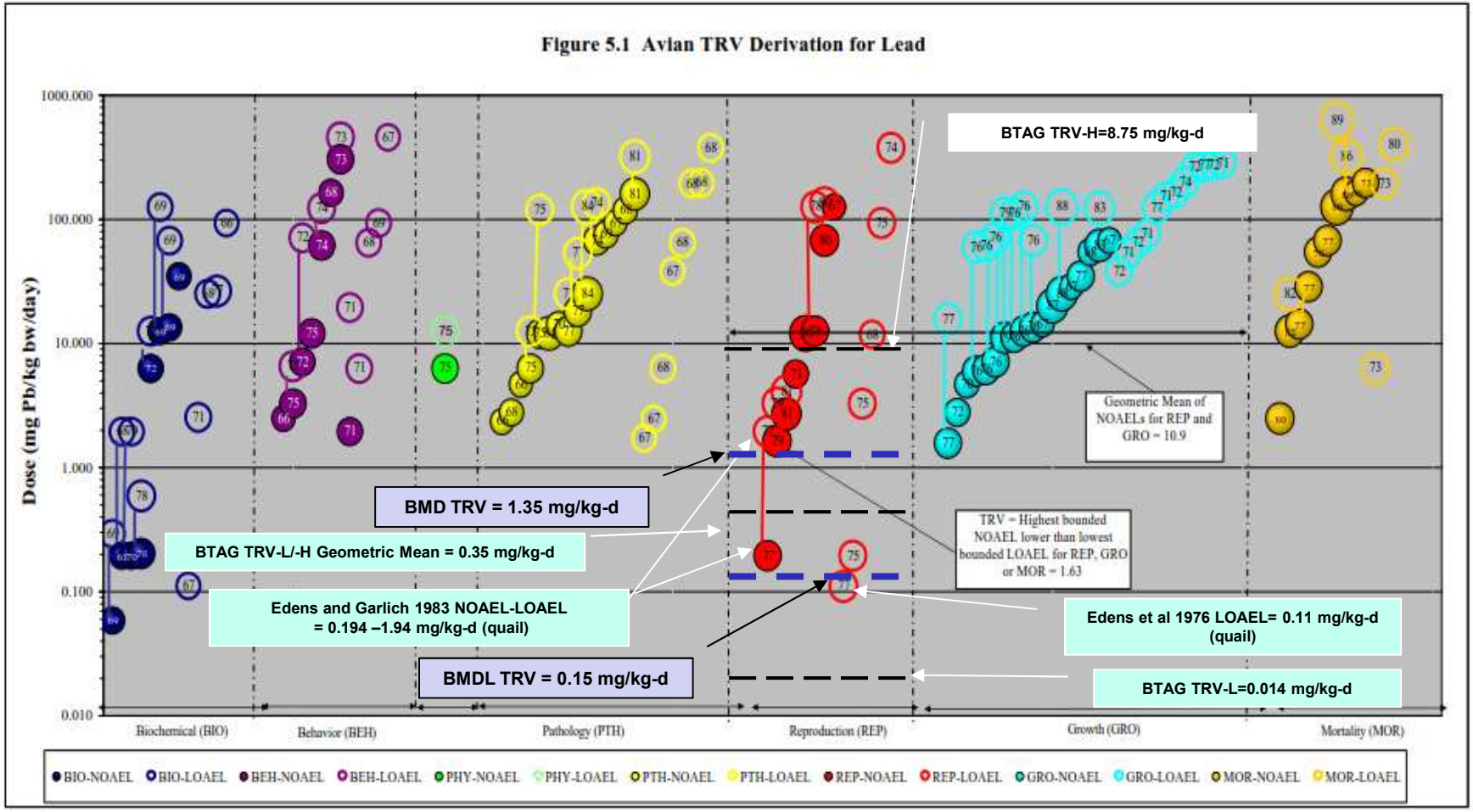
- BMD selected is analogous to an EC10 effect level. This is appropriately protective of a special-status species.
  - EC10 is a low-effects concentration that can be used as a surrogate for a no effect level (NOAEL)
    - Statistically non-significant, yet measurable effects relative to a laboratory control are on the order of 10-20%
    - The 10% effects level (EC10) commonly falls within the “noise level” of control group response
    - The 20% effects level (EC20) indicates *de minimus* effect response predictive of onset of effect
- TRVs from the D-R curve were selected and used as input in the PCL calculation.
  - Benchmark Dose (BMD): dose associated with a specified measure or change of a biological effect
  - Benchmark Dose Lower Bound (BMDL): lower one-sided 95% confidence limit on the BMD

BMD Model Output



Benchmark Dose mg/kg food	TRV mg/kg-d	Basis
1.07 mg/kg	0.15	95% Lower Confidence Limit of BMD (BMDL)
9.63 mg/kg	1.35	BMD

Summary of Literature Avian Lead NOAEL/LOAEL TRVs and BMD TRVs



Revised Lead PCL for CLT

Parameter	Source	Adult	Juvenile	Hatchling
Exposure Assumptions				
Food Intake Rate (FIR, kg/kg-d)	Nagy 2001	0.223	0.223	0.346
Soil Proportion in Diet (P_s, unitless)	CH2M Hill 2002	0.02	0.02	0.02
Seasonal Use Factor (SUF, unitless)	TDS 2002	0.41	1	1
Absorbed Fraction (AF, unitless)	Kaufman et al 2007	0.53	0.53	0.53
TRV (mg/kg-d)				
BMDL TRV	Calculated	0.15	0.15	0.15
BMD TRV	Calculated	1.35	1.35	1.35
PCL (mg/kg)				
PCL based on BMDL	**Calculated**	**155**	**63**	**41**
PCL based on BMD	**Calculated**	**1,393**	**571**	**368**

Protective Concentration Implementation

- Based on the PCLs developed for the three CLT life stages below:
  - Hatchling = 41 mg/kg soil
  - Juvenile = 63 mg/kg soil
  - Adult = 155 mg/kg soil
- A desk-top removal exercise was conducted and confirmed that removing soil with lead exceeding the Adult PCL (155 mg/kg) would achieve a site-wide exposure point concentration (EPC) of less than 41 mg/kg.
- Adopted Approach
  - Use the Adult PCL as a “Do Not Exceed” value
  - Use the Hatchling PCL as a target site-wide EPC

Knowledge Check

What are the primary benefits of using BMD?

a) Reduce uncertainty
b) Lowers your clean up goal
c) Allows you to better understand the dose response relationship, enabling you to better estimate the effects concentration

What is the BDML value?

a) 95% lower confidence limit of the BDM
b) Gives additional certainty that a cleanup value will be protective
c) 95 times lower than the BDM value

Summary

- State Regulators push for the lowest TRVs (BTAG Low – NOAELs) to develop cleanup values - especially in cases where endangered species are present.
- Use of BTAG-Low may result cleanup values below background/ anthropogenic values and sometimes background may be too low to use as a cleanup value.
- Dose-Response methodology was used in a manner to develop a reasonable conservative avian lead TRV.
  - TRVs derived using EPA BMD model are conservative thresholds protective of special-status species.
  - Provides alternative TRVs that produce a practical and reasonable PCL in the absence of an agreed upon ambient concentration for lead.
- BMD evaluations are dependent on having a good and representative dose-response data set.

Contacts and Questions

Points of Contact

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Questions ?

EXTRA SLIDES

Supplemental Information

References

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Lead Background Assessment

- NASNI Metals background was developed and adopted in 1995.
  - The 99th percentile values was acceptable for risk screening
  - Outliers were discussed and removed from the data package after reaching a consensus.
  - High lead levels due to the impact of AVGAS use would be clearly designated as “ambient” and the background values would be specific to North Island sites
  - Lead background value of 405 mg/kg was adopted.
- Site 9 is adjacent to the airfield
- The regulatory agencies indicated the use of the value would not be protective and repudiated the use of the 1995 background value.
- A subsequent evaluation of same data set using EPA’s ProUCL program yielded a lead background values of 233 mg/kg.
- Regulatory agencies indicated that the recalculated background lead value would not be protective.

Examples of D-R Methods Used

- **California**
  - URS 2014. Dose-response curve based on site-specific toxicity testing used to develop point estimate thresholds for aquatic organisms for a chemical mixture. Reviewed and accepted by California State Water Resources Control Board.
  - Department of Pesticide Regulation's Draft Risk Characterization Document for 1,3-Dichloropropene.
- **New York**
  - Development of Sediment Remediation Goals for the Onondaga Lake, NY Superfund Site (Earth Tech, EPA, NYDEC 2005) – used D-R relationships for benthic invertebrates to develop cleanup goals.
- **EPA**
  - Ambient water quality criteria developed based on D-R relationships in literature; EC20s historically used in development of NAWQC.
  - 2016 Selenium NAWQC based on EC10 for reproductive endpoint in fish, which is considered a no effect level.
  - Used in developing RfD, RfC, and cancer slope factors for human health risk assessment.

Development Dose-Response Curve

- EPA Benchmark Dose (BMD) Software Version 2.6.0.1 (EPA 2015) tool was used to develop dose-response curve
- Per EPA BMD Technical Guidance (EPA 2012), a benchmark dose is:
  - *Exposure due to a dose of a substance associated with a specified low incidence of risk, generally in the range of 1% to 10% of a health effect; or dose associated with a specified measure or change of a biological effect"*
- Key BMD Inputs (EPA 2015)
  - Dose
  - Number of subjects
  - Mean response (per dose group) OR individual animal responses
  - Measure of variability in response (standard deviation – SD)
  - Effect level (e.g., EC10, EC50)

Critical Review of BTAG TRV-L for Lead

- Region 9 BTAG TRV-L based on:
  - Unbounded lowest effect level (0.14 mg/kg-d) adjusted downward using an uncertainty factor (UF=10) to estimate a no effect level → BTAG TRV-L (0.014 mg/kg-d)
- Avian BTAG TRV-L for lead is overly conservative for use in PCL development
  - Recommended use of BTAG TRVs is to characterize risk, and development of remediation goals should integrate other information (DTSC EcoNote 4, DTSC 1996)
  - Use of generic UF to convert effect to no effect:
    - UFs lack robust technical basis and should not be used without scientific justification (Allard et al 2009)
    - UFs are intended to provide conservative values for use in screening level assessments
  - Use of BTAG TRV-L for lead results in PCLs below typical ambient conditions (DTSC EcoNote 4)
    - At other sites where lead cleanup values are below ambient concentrations, cleanup goals are set at ambient
    - No agreed-upon ambient concentrations for lead at NAS North Island; therefore, extremely low lead PCLs are not practical for cleanup purposes
  - Other standard, no-effect TRVs are significantly higher (e.g., EcoSSL) than the Region 9 BTAG TRV-L

Use of EPA's BMD Model

- BMD Technical Guidance (USEPA 2012) presents framework for consistent application of BMD evaluations including:
  1) Determination of studies and endpoints on which to base BMD calculations;
  2) Selection of the benchmark response value;
  3) Choice of the model(s) to use in computing the BMD;
  4) Model fitting, assessment of model fit, and model comparison;
  5) Computation of the confidence limit for the BMD (i.e., the BMDL); and
  6) Reporting recommendations for the presentation of BMD and BMDL computations.

Key Development Study Selected

- Edens et al 1976
  - Japanese quail exposed to highly soluble lead acetate in food from day of hatch to 12 weeks of age. Reproductive, growth, and biochemical endpoints were measured.
- Edens et al 1976 selected because:
  - It is a conservative study for TRV development
    - Japanese quail are most sensitive species in Eco-SSL dataset
    - Represents lowest effect concentration in Eco-SSL dataset
    - 1ppm lead in food resulted in significant decrease (a 10% reduction versus control) in setable eggs (eggs/hen/week)
  - Exposure duration, life stage, and toxicological endpoints are appropriate
  - Subsequent study (Edens and Garlich 1983) showed similar results for the quail
  - Chosen to be consistent with study from which Region 9 BTAG Avian TRV-L was developed
  - Doses, response, number of test animals, and statistics provided in the study were sufficient to develop a D-R relationship

Uncertainty Evaluation

- Selected Toxicity Study:
  - Relevance of dosing regime
    - Quail continually dosed for 12 weeks from hatch through egg laying.
    - CLTs exposed at site through hatchling and juvenile period, then leave nesting site (within 10-12 weeks of hatching) and do not return to lay eggs for 2-3 years (Thomson et al. 1997).
    - Unclear whether dosing at an early age, then extended period of *de minimus* exposure, would result in reduction in setable eggs.
    - Removal of lead exposure - Eden's and Garlich 1983 (Experiment 4) found that egg laying increased in 2 of 3 treatment groups once lead dosing stopped, suggesting that adverse effect may be reversible once dosing stops.
- D-R Model
  - Selecting best fit model: numerous lines of evidence were used to select a best fit model thereby reducing uncertainty

Uncertainty Evaluation

- Selected Toxicity Study: Most conservative study selected
  - Relevance of test species (quail) to CLT
    - Age at sexual maturity - Quail reach sexual maturity at about 6 weeks of age; terns at about 2-3 years of age.
    - Reproductive endpoint relevant for young birds/adults that are or will be producing eggs soon. Likely that CLT reach sexual maturity in their 2nd/3rd year at the site.
  - Relevance of selected endpoint
    - Number of setable eggs may not be relevant for hatchlings and juveniles.
    - Delay in age at first egg more relevant - Per Edens et al 1976, doses ≥10ppm resulted in increased age to first egg that were significant relative to control. This results in a TRV for hatchlings similar to the BMD TRV of 1.35 mg/kg-d.